

ANALYTICAL RESEARCH LABORATORIES

840 RESEARCH PARKWAY, SUITE 546

OKLAHOMA CITY, OK 73104

PHONE (405) 271-1144

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Certificate Of Analysis

CLIENT: New England Compounding Center

ARL #: 185270-01

LOT #: 08202012@101

DESCRIPTION: Ropiv 0.5%-Epi 1:1000- Ketor 30mg/mL-Clon PF 0.1mg/mL- Pericapsular Injection

DATE RECEIVED: 08/22/2012

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two syringes (3 mL, 10 mL)

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Ropivacaine HCl Specifications = 90% - 110%	0.447	%	0.450	100.7%	HPLC	8/24/2012
Epinephrine Specifications = 90% - 115%	1.0	mg	Not Detected		HPLC	8/28/2012
Ketorolac Tromethamine Specifications = 90% - 110%	0.054	%	0.04945	91.6%	HPLC	8/27/2012
Clonidine Specifications = 90% - 110%	0.000147	%	0.000139	94.6%	HPLC	8/24/2012

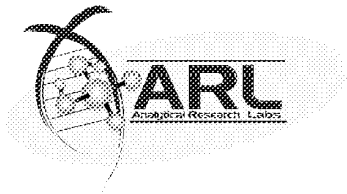
Alex Tang - Laboratory Supervisor

09/04/2012

Date Reported

ARL Form QUF-078-V4 03/05/2010

Results reported above relate only to the sample that was tested.



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Microbiology Report

CLIENT: New England Compounding Center

ARL #: 185270-01

LOT #: 08202012@101

DESCRIPTION: Ropiv 0.5%-Epi 1:1000- Ketor 30mg/mL-Clon PF 0.1mg/mL- Pericapsular Injection

DATE RECEIVED: 08/22/2012

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two syringes (3 mL, 10 mL)

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)		No Growth at 7 Days	USP 71	08/22/2012
Endotoxin	No USP Limit	<6.39 EU/mL	USP 85	08/27/2012

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: K is $175/V$ or Intrathecal radiopharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²/70 Kg.

Amar Arafat - Microbiologist

08/27/2012

Date Reported

ARL Form QUF-078-V5 08/20/2012

Results reported above relate only to the sample that was tested.